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August 6, 2004

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*BY ELECTRONIC AND REGULAR MAIL*

Ms. Kathleen Ellwood  
Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling and  
Dietary Supplements  
CFSAN, U.S. Food and Drug Administration  
Room 4A026, HFS-830  
5100 Paint Branch Parkway  
College Park, MD 20740

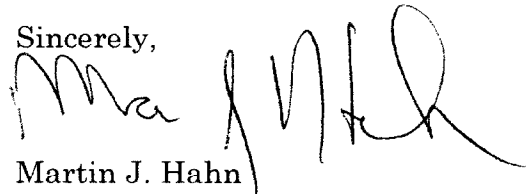
**Re:** Health Claim Petition: Dietary supplementation of Crystalline  
Glucosamine Sulfate (Glucosamine Sulfate Sodium Chloride-USP/NF  
2003) reduces the risk of osteoarthritis joint deterioration and related  
joint pain and limitation of function.

Dear Ms. Ellwood:

We are writing this letter on behalf of our client, Rotta  
Pharmaceuticals Inc. (Rotta). Rotta agrees to extend the agency review period for  
the above-referenced health claim until September 10, 2004, as requested by Daniel  
E. Troy, Esq., Associate General Counsel, during our telephone conversation on  
August 3<sup>rd</sup>

If you have any questions, please contact us.

Sincerely,



Martin J. Hahn

cc: Daniel E. Troy, Esq.  
Gloria J. Overholser, Esq.

2004P-0060

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